Remarks

Examiner has requested applicants to elect one of the following groups of claims:

Group 1, claims 1-7, 23-25, 27, drawn to the polypeptide SEQ ID NO: 6, a fragment thereof, and a method for detecting cancer, by detecting SEQ ID NO: 6.

Groups 2-9, claims 1-7, drawn to the polypeptide SEQ ID NO: 7-11, 22-24, and a fragment thereof. Each polypeptide constitutes a single, distinct invention.

Groups 10-18, claims 8-12, drawn to an antibody to the polypeptide SEQ ID NO: 6-11, 22-24. An antibody to each polypeptide constitutes a single, distinct invention.

Groups 19-23, claims 13-15, drawn to a nucleic acid SEQ ID NO: 1-5. Each nucleic acid constitutes a single, distinct invention.

Group 24, claims 18-19, drawn to a method for inducing CTL, using the peptide SEQ ID NO: 12.

Group 25, claims 20-21, drawn to a method for treating cancer, using CTLs specific for SEQ ID NO: 12.

Groups 26-34, claim 22, drawn to the immunogen SEQ ID NO: 13-21. Each immunogen constitutes a single, distinct invention.

Groups 35-39, claims 23-26, drawn to a method for detecting cancer, using the nucleic acid SEQ ID NO: 1-5. A method using each nucleic acid constitutes a single, distinct invention.

Groups 40-47, claims 23-25, 27, drawn to a method for detecting cancer, by detecting SEQ ID NO: 7-11, 22-24. A method detecting each polypeptide constitutes a single, distinct invention.

Group 48, claims 16-17, 28-30, drawn to a host cell, or an antigen presenting cell, expressing the polypeptide SEQ ID NO: 6.

Groups 49-56, claims 16-17, 28-30, drawn to a host cell, or an antigen presenting cell, expressing the polypeptide SEQ ID NO: 7-11, 22-24. Examiner asserts that a host cell expressing each polypeptide constitutes a single, distinct invention.

Response to Restriction Requirement

Election

In the opinion of the Examiner, Groups 19-23, claims 13-15, are drawn to nucleic acids having SEQ ID NO: 1-5 and each nucleic acid constitutes a single, distinct invention. Applicants hereby provisionally elect **Group 19** (claims 13-15), drawn to a nucleic acid having the sequence of **SEQ ID NO:1**, with traverse. Reconsideration of the Restriction Requirement in all aspects is requested in view of the following remarks.

Examiner's Position

Examiner asserts that there is lack of unity of invention among the claims and further asserts that there are 56 Groups. Examiner cites PCT article 17(3)(a) and 37 CFR 1.476(c), 37 CFR 1.475(b) and 37 CFR 1.475(d).

Rules Governing Examination of Claims and Unity

MPEP 1893.03 states that prosecution of an international application which enters the national stage in the US under 35 U.S.C. 371(c) must proceed with unity of invention as under 37 C.F.R. 1.475. 37 C.F.R. 1.475 has no provision which allows restriction practice to revert to that used for domestic U.S. applications; thus Examiner must proceed with the requirement for unity of invention as defined in this section.

Unity of invention under PCT Rule 13 is satisfied when there is a technical relationship among those inventions defined by the claims which involves "one or more of the same or corresponding special technical features". PCT Rule 13 does not prohibit product and process of use claims from being examined in a single application, even if both the claimed product and process can be used separately, in materially different ways. Rather, PCT Rule 13 allows for such claims to be examined together in a single application if all claims contain the same or similar technical feature. This unifying special technical feature is that which defines a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. PCT Rule 13.2 and the PCT Administrative Instructions, Annex B, Part 1(b).

Applicants point out that PCT Rule 13.2 states that "[t]he expression "special technical features" shall mean those technical features that define a contribution which each

of the claimed inventions, **considered as a whole**, makes over the prior art." (emphasis added). Applicants respectfully submit that Examiner has not considered the claims as a whole. 37 C.F.R. 1.475(a) requires that the special technical must be considered as a whole over the prior art.

Additionally, PCT Rule 13.3 requires that the determination of whether groups are so linked as to form "a single general inventive concept **shall** be made **without regard to whether the inventions are claimed in separate claims or a alternatives within a single claim.**" (emphasis added). Thus, PCT Rule 13.3 reinforces the requirement of considering the claims as a whole.

Where a single patent application contains claims of different categories, the claims have unity of invention when claims contain a special technical feature, and the claimed manufacturing process is specifically adapted to produce the claims product. A process is specifically adapted" for the manufacture of a claimed product when that process inherently results in the product. PCT Administrative Instructions, Annex B, Part 1(e)(1). According to the PCT Administrative Instructions, Annex B, Part 1(e)(iii), "[t]he words "specifically adapted' are not intended to imply that the product could not also be manufactured by a different process. Thus, the Examiner need only consider whether claims of different categories contain the same or corresponding special technical feature, and whether the claimed process of manufacture inherently produces the claimed product.

The present case is analogous to several examples of the PCT Administrative Instructions, Annex B, Part 2(I). Example 3 of Annex B provides three independent claims: Claim 1 to a process for using substance X (here represented by the methods of detecting cancer using peptides and nucleic acids); claim 2 to substance X (here represented by the nucleic acid and peptide sequences); and claim 3 to an apparatus (no need for this here because there is no apparatus). According to the rules, claims 1 and 2 have unity, as does claim 3. Example 4 of Annex b provides 2 claims which have unity under the rules. Claim 1 to a family of compounds X (here represented by the nucleic acid sequences and peptide sequences); and claim 2 to compound X_1, belonging to family X (here represented by the specific sequences of each family). Example 17 of Annex B provides that a **protein and a**

DNA sequence encoding it also share unity (represented here by Group 1, Groups 2-9, Groups 19-23, Groups 35-39, and Groups 40-47; for example, the protein of SEQ ID NO:6 is encoded by the nucleic acid of SEQ ID NO:1, and so on for comparing SEQ ID NOs:).

Claims which possess a unifying special technical feature and which are drawn to a product and a process of use of said product have unity of invention. 37 C.F.R. 1.475(b)(2).

According to the new PTO guidelines entitled "Examination of Patent Applications Containing Nucleotide Sequences" signed in February, 2007,

> "For International applications and national stage filings of international applications under 35 U.S.C. 371, unity of invention determination will be made in view of PCT Rule 13.2, 37 CFR 1.475 and Chapter 10 of the ISPE Guidelines. Unity of invention will exist when the polynucleotide molecules, as claimed, share a general inventive concept, i.e., share a technical feature which makes a contribution over the prior art."

Applicants assert that there is unity of invention under the PCT rules and ISPE Guidelines regarding searching sequences. That is, the same general inventive concept exists, as the peptides and the nucleic acids encoding the peptides have the same use in the claims, the sequences share the same technical feature regarding structure.

Specific Requests for Rejoining Groups

1. Applicants request that the nucleic acid sequences having SEQ ID NOs:2-5 (Groups 20-23, claims 13-15) be rejoined with SEQ ID NO:1 (Group 19, claims 13-15), the sequence which has been elected herein, because SEQ ID NOs:2-5 are not unrelated to SEQ ID NO:1 and because they share the same inventive concept. For example, the nucleic acid sequences of SEQ ID NOs:1-5 each share a common 196 base sequence at the 5' ends of each of the five sequences. That 196 base sequence shared by each of SEQ ID NOs:1-5 is:

ctccacaccgccttgcaagctgagggagccggctccggcctctgccagcccaggaaggggctcccacagtgcagcg gcgggctgaaggactcctcaagtgccaccaaagtgggagcccaggcagaggaggcgccgagagcgagcgagggctgcctgcc agcacgctgtcacgtctcagcaatagactgctcttgag.

Evidence for the unity of these sequences and relatedness with regard to searching can be found in the specification as filed, for example, in the sequence listing, page 5, lines 9-15, and at page 10, lines 18-20.

Thus, there is unity of invention among these five nucleic acid sequences because of the shared sequence which is a contribution over the art, satisfying PCT Rules 13.1, 13.2 and 13.3, as outlined above. Furthermore, there would be no undue burden on the Examiner to search the five sequences together, because a search of the common 196 base sequence would necessarily uncover art for all five of the nucleic acid sequences having SEQ ID NOs:1-5. For these reasons, Applicants request that SEQ ID NOs:2-5 (Groups 20-23) be rejoined with SEQ ID NO:1 (Group 19).

Applicants assert that there is unity of invention under the PCT rules and ISPE Guidelines regarding searching sequences having SEQ ID NOs:1-5. That is, the same general inventive concept exists, as the peptides and the nucleic acids encoding the peptides have the same use in the claims, the sequences share the same technical feature regarding structure.

2. Applicants assert that Group 1 (claims 1-7, 23-25, and 27), drawn to the polypeptide SEQ ID NO:6 and a method of detecting cancer (which Examiner admits has unity of invention), should be rejoined with Group 19 (elected above), because the nucleic acid of SEQ ID NO:1 of Group 19 (the group elected for prosecution herein) is a nucleic acid sequence which encodes the polypeptide of SEQ ID NO:6. Groups comprising a peptide having an amino acid sequence encoded by a nucleic acid sequence under examination, should be rejoined with the nucleic acid sequence under examination. Group 19, and Groups 20-23 as requested and discussed above, i.e., Example 17 of Annex B provides that a **protein and a DNA sequence encoding it also share unity**. Evidence for relatedness and unity of the nucleic acid and peptide sequences can be found in the specification at, for example, page 10, lines 16-30, and at page 12, lines 12-20.

Applicants assert that there is unity of invention under the PCT rules and ISPE Guidelines regarding searching and combining peptide sequences and the nucleic acid sequences which encode them. That is, the same general inventive concept exists, as the

peptides and the nucleic acids encoding the peptides have the same use in the claims, the sequences share the same technical feature regarding structure.

3. Applicants also assert that SEQ ID NOs:7-11 and 22-24 of Groups 2-9 should be rejoined with SEQ ID NO:6 of Group 1 because the sequences are related to a single inventive concept. For example, the peptide sequences of SEQ ID NOs:6-11 all share the 39 amino acid sequence:

ThrLeuSerArgLeuSerAsnArgLeuLeuLeuArgLeuGluCysAsnValValIleIle AlaHisCysAsnLeuGluProLeuValSerArgAspProProAlaSerAlaSerLeu (emphasis added).

Additionally, the peptide sequences of SEQ ID NOs:22-24 share the first 11 amino acids of the sequence listed above (as indicated by the underlined sequence), namely ThrLeuSerArgLeuSerAsnArgLeuLeuLeu, with sequences having SEQ ID NOs:6-11.

Thus, all the peptides of SEQ ID NOs:6-11 and 22-24 share common sequences which confer a special technical feature over the art, when the sequences are considered as a whole. Moreover, according to the new PTO guidelines and the MPEP there is no reason not to include in a search multiple sequences which share common sequences, as is the case here for both the peptides represented by SEQ ID NOs:6-11 and 22-24. In fact, as described above the guidelines provide for such a search. Therefore, Applicants submit that it would not be burdensome for the Examiner to search both SEQ ID NOs: 6-11 and 22-24, because searching one would necessarily uncover relevant art for the others, and request that the Examiner search both and rejoin the peptide sequences together, as well as rejoin the peptide sequences with the nucleic acid sequences as described above. That is, Groups 2-9 should be rejoined with Group 6, and as described above, Group 6 should be rejoined with Group 19, and Groups 20-23 should be rejoined with Group 19.

4. Applicants assert that Group 35, drawn to a method of detecting cancer using a nucleic acid having SEQ ID NO:1, should be rejoined with Group 19, for the reasons described above. Additionally, Groups 36-39, drawn to a method of detecting cancer using SEQ ID NOs:2-5 should be rejoined with Group 35, and also Group 19, for reasons described above.

5. Applicants further assert that Groups 40-47 (claims 23-25, 27) drawn to a method of detecting cancer, by detecting peptides having SEQ ID NOs:7-11 and 22-24 should be rejoined with Groups 19 and 1 for the reasons described above.

Conclusion

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (434) 243-6103.

Respectfully submitted,

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